

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

<p>AMGEN INC.,</p> <p style="text-align: center;">Plaintiff,</p> <p style="text-align: center;">v.</p> <p>AMNEAL PHARMACEUTICALS LLC, et al.,</p> <p style="text-align: center;">Defendants.</p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	<p>Civ. No. 16-853-MSG CONSOLIDATED</p>
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ORDER

After an appeal and remand from the United States Court of Appeals for the Federal Circuit, four issues are left for this Court to decide. First, is the request of Defendant Piramal Healthcare UK Ltd. (“Piramal”) to recover damages from the injunction bond that Plaintiff Amgen, Inc. (“Amgen”) posted in the amount of \$39,000,000 pursuant to Fed. R. Civ. P. 62(d).¹ Applying the Federal Circuits claim construction for the *Markush* groups, the second issue is whether the accused product of Defendant Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York LLC (collectively, “Amneal”) meets the disintegrate limitation in United States Patent No. 9,375,405 (the “’405 patent”). The third issue is whether Amneal’s formulation meets the binder limitation in the ’405 patent because it contains “from about 1% to about 5% by weight” of hydroxypropyl methylcellulose (“HPMC”), irrespective of the HPMC’s pairing with polyethylene

¹ Following the Court’s judgment of non-infringement in favor of Piramal and against Amgen (D.I. 386) and Amgen’s Notice of Appeal (D.I. 397), Amgen filed an Emergency Motion for Preliminary Injunction Pending Appeal (D.I. 430), which Piramal opposed (D.I. 447). Subsequently, the Court entered a Stipulated Order enjoining Piramal and its marketing partner, Slate Run Pharmaceuticals, LLC, from selling or offering for sale Piramal’s cinacalcet tablets until, among other events, the Federal Circuit issued a mandate affirming the Court’s Judgment (D.I. 462). The Stipulated Order required Amgen to post a bond in the amount of \$39,000,000 pursuant to Fed. R. Civ. P. 62(d), which Amgen later did (D.I. 476).

glycol (“PEG”). And, finally, I must decide Amneal’s invalidity counterclaims.²

On June 11, 2020, I held a joint status conference and, on June 25, 2020, the parties submitted a joint status report setting forth their proposed procedures and competing schedules for resolving the remaining issues. *See* D.I. 497; D.I. 498.

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. Piramal’s damages case will proceed according the following schedule:
 - a. Piramal shall serve its damages contentions by **July 15, 2020**;
 - b. Fact discovery, including, but not limited to, document discovery, interrogatories, depositions, and third-party discovery closes **August 6, 2020**;
 - c. Piramal shall serve its opening expert reports by **September 3, 2020**;
 - d. Amgen shall serve its responsive expert reports by **October 1, 2020**;
 - e. The parties shall submit a joint letter to the court by **October 10, 2020** that suggests a specific number of hours for the December hearing, identifies all witnesses who will testify, at the hearing, states whether those witnesses will be testifying live or by other means, and if applicable, identifies those other means.
 - f. Piramal shall serve its reply expert reports by **October 15, 2020**;
 - g. Expert depositions shall be completed by **October 29, 2020**;
 - h. Piramal shall file and serve its opening brief by **November 2, 2020**;
 - i. Amgen shall file and serve its responsive brief by **November 23, 2020**;
 - j. Piramal shall file and serve its reply brief by **December 7, 2020**;
 - k. A pre-hearing teleconference will be held on **December 9, 2020 at 10:00 a.m.** The parties will provide the court with dial in details at least two business days before the conference via email to chambers_of_judge_mitchell_s_goldberg@paed.uscourts.gov.
 - l. A hearing will be held the week of December 14, 2020. Location and courtroom to be determined.

² After entering a judgment of non-infringement in favor of Amneal and against Amgen, Amneal’s invalidity counterclaims were dismissed without prejudice as moot. *See* D.I. 384 ¶ 1.

2. Amneal's infringement and invalidity case will proceed according to the following schedule:

- a. Amneal shall serve supplemental opening expert reports on the issue of invalidity by **September 30, 2020**;
- b. Amgen shall serve supplemental responsive expert reports on the issue of validity and raises any secondary considerations of non-obviousness it wishes to rely on at trial by **November 16, 2020**;
- c. Amneal shall serve responsive expert reports rebutting any secondary consideration(s) of non-obviousness by **December 4, 2020**;
- d. The parties shall submit a joint letter to the court by **December 11, 2020** identifying proposed dates for a trial, suggesting a specific number of hours for the trial, identifying all witnesses who will testify and whether those witnesses will be testifying live or by other means, and if applicable, identifying those other means;
- e. Supplemental expert depositions shall be completed by **January 31, 2020**; and
- f. The parties' supplement pretrial exchanges shall be completed by **March 15, 2021**.

Dated: June 30, 2020

BY THE COURT:

/s/ Mitchell S. Goldberg
MITCHELL S. GOLDBERG, J.